BI3

FINANCIAL IMPACT OF HOSPITAL EXPENDITURE IN CHRONIC DISEASES FOR SEGURO POPULAR

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OBJECTIVES: Estimate the expenditure in hospital services for cardio-vascular (CVD), malignant tumors (MT) and diabetes financed by Seguro Popular (SP) for 2004-2012 in order to evaluate its midterm financial sustainability. **METHODS:** Hospital costs for interventions financed by SP for year 2012. Related hospital discharges from the SAEH for 2004-2012. Multiplication of both data generated the cost per ICD-10. The product was then grouped by GBD. Total hospital expenditure for SP, obtained from SINAIS for 2004-2012, was distributed using the cost per GBD. Then the proportion of hospital expenditure related to CVD, MT and diabetes is estimated. **RESULTS:** Mexico is one of the countries with the highest prevalence of child and adult overweight and obesity (O&O). That situation imposes a great pressure into SP to face an increasing demand of health care for non-communicable chronic diseases (NCD) particularly diabetes, MT and CVD. The average annual hospital expenditure of these groups of diseases represents about USD$273.4 million in 2012 (9.7% of hospital expenditure). Malignant tumors that contributed the most were breast and cervical cancer with 90% of the total expenditure for this group. Acute myocardial infarction represents 66% of total expenditure for cardio-vascular. Under the status quo an increase of 65% in the cost of this group of diseases is expected for 2018. **CONCLUSIONS:** Findings show an increased financial burden for SP generated by the selected NCD. The impact on the public budget that represents this level of hospital expenditure would threaten the sustainability of the SP if current trends hold. Given the demographic transition and level of O&O as risk factors for developing NCD in the coming years it is necessary to strengthen prevention and health promotion to reduce both new cases of NCD and complications in order to decrease their future impact on the SP budget.

BI4

HOSPITALIZATION COSTS OF TYPE 2 DIABETES MELLITUS (T2DM) PATIENTS IN A PUBLIC HOSPITAL IN BRAZIL

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OBJECTIVES: Diabetes is considered an outpatient care condition, manageable in the primary care setting, but which complications may lead to hospitalization. There is limited data on the costs of patients hospitalized due to diabetes in Brazil. We aimed to estimate the percentage of type-2 diabetes mellitus (T2DM) patients who were hospitalized and the mean cost per hospitalization within a public hospital in Brazil (SUS). **METHODS:** T2DM outpatients followed at the Hospital das Clínicas of Universidade Federal do Paraná (HC-UFPR) between 2011 and 2014 were eligible. Data from the last year of treatment were collected and validated within medical charts. We assessed demographics, hospitalization and cause, length and average costs per day of hospitalization. Exchange rate was 1.00USD = 3.21BRL. The study was approved by HC-UFPR IRB. **RESULTS:** A total of 728 patients with T2DM were evaluated, of which 38 (5.2%, 22 females and 17 males) were hospitalized due to eight different causes. Mean age was 64 years (44 to 84). Main reason for hospitalization was cardiovascular related problems (58.5%), followed by decompensated diabetes treatment (17.0%) and kidney problems (9.4%). Average daily cost ranged from 907BRL (~283USD) (Neurology Center) to 2218BRL (~691USD) (Intensive Cardiology Therapy Center). The amount spent on the Cardiology Center represented 27.5% (188,244BRL) (~58,643USD) of the total, followed by Intensive Cardiology Therapy Center with 18.1% (124,189BRL) (~38,688USD). Total hospital spending with 38 hospitalizations was 685,058BRL (~213,414USD) and mean length of hospitalization was 10 days (1 to 30 days). Mean cost per patient was 18,028BRL (~5,616USD). **CONCLUSIONS:** Hospitalized patients with T2DM represent a significant burden to healthcare payers. However, the amount spent by the hospital is not necessarily the same reimbursed by the Brazilian Public Healthcare System (SUS), which hinders the estimate of the burden for the system as a whole.

CARDIOVASCULAR DISEASE & DIABETES RESEARCH STUDIES

CV1

ASSOCIATION OF ADHERENCE STATUS AS MEASURED USING TWO SINGLE-ITEM PHYSICIAN-ADMINISTERED METHODS WITH CARDIOVASCULAR RISK IN PATIENTS TAKING ANTIHYPERTENSIVE MEDICATION

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OBJECTIVES: In patients with hypertension, non-adherence to prescribed treatment may contribute to a significant increase in cardiovascular risk. The aims of this study were (1) to examine if two single-item physician-administered adherence scales are predictive of cardiovascular risk and (2) to evaluate whether adherence to antihypertensive medications is associated with at least a one percent reduction in cardiovascular risk over 90 days. **METHODS:** Pooling data from seven observational studies, this analysis included 8,438 hypertensive patients taking valsartan. A ten-year cardiovascular risk (CVR) score was estimated following the risk scoring system proposed by the SCORE project in Europe. CVR score considered the following variables: age, total cholesterol, current smoking status, systolic blood pressure, and sex. At baseline and 90 days, physicians administered two single-item measures of adherence: the first item of the Basel Assessment of Adherence Scale (BAAS) and the Visual Analogue Scale (VAS). **RESULTS:** At 90 days, males (4,257) had a significantly higher CVR than females (4,091) (p<0.001). For BAAS-identified adherent patients, CVR decreased significantly by 2.6% from baseline to 90 days (p-value<0.001). For BAAS-identified non-adherent patients, a significant but smaller decrease in CVR of 1.3% was observed (p<0.001). For VAS-identified adherent patients, CVR decreased significantly by 4.4% from baseline to 90 days (p<0.001). However, a significant decrease of 4.3% (p<0.001) was also observed for VAS-identified non-adherent patients. **CONCLUSIONS:** Patients identified as adherent using the first item of the BAAS showed significantly improved 10-year cardiovascular risk scores after 90 days of treatment with valsartan, compared to patients who were identified as non-adherent. The VAS scale was not sufficiently sensitive to determine the effect of adherence on cardiovascular risk score.

CV2

APIXABAN IN PATIENTS WITH ATRIAL FIBRILLATION: PATIENT CHARACTERISTICS OF THE LATIN AMERICA COHORT FROM A MULTINATIONAL CLINICAL TRIAL

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OBJECTIVES: Patients with Atrial fibrillation (AF), have a five-fold increase in the risk of stroke. Treatment for AF include stroke prevention therapy. Vitamin K antagonists (VKAs) have shown to prevent stroke in AF patients. Apixaban, a novel oral direct factor Xa inhibitor was studied in AF patients whom VKA therapy was unsuitable. Apixaban demonstrated clinical benefit in stroke or systemic embolism reduction without impacting the risk of major bleeding or intracranial hemorrhage. Patient characteristics of the Latin America (LA) cohort and overall population are presented. **METHODS:** Patients with AF at an increased risk for stroke and whom VKA therapy was unsuitable were randomized to receive apixaban (5 mg twice daily) or aspirin (81 to 324 mg) in a double blind trial. The study recruited from 36 countries from September 2007 through December 2009. Five countries were from LA: Argentina, Brazil, Chile, Colombia, and Mexico. Patient characteristics from the LA cohort, is presented relative to the overall trial population. **RESULTS:** Of5599 patients in the trial, 1185 were from LA (21.2%). Mean age was similar, 71.5 and 70 for LA and overall cohort respectively. 55% and 58% were males for LA and overall cohort respectively. The LA and overall cohorts had similar rates of prior stroke or TIA, diabetes mellitus and hypertension receiving treatment, at enrollment. Mean CHADS2 score at enrollment was 2,.0 for the apixaban arm and 2.1 for the ASA arm, which is the same for cohorts. Other baseline characteristics were similar. Region subgroup analysis revealed no statistically significant (p> 01.0) interactions between treatment effects and geographic region. **CONCLUSIONS:** Baseline demographic and disease characteristics data from the LA cohort were similar to that of the clinical trial population. Results, in terms of safety and efficacy, given the total population trial, are expected to be consistent since interaction between treatment effects and geography was not significant.

CV3

ARETAEUS: RETROSPECTIVE STUDY OF MEDICATION USAGE PATTERNS FOLLOWING THE DIAGNOSIS OF TYPE 2 DIABETES IN LATIN AMERICA

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OBJECTIVES: To examine the initiation of oral antihyperglycemic agents (OAHAs) and/or statins in patients with type 2 diabetes mellitus (T2DM) and assess the time elapsed from diagnosis to treatment initiation and intensification when goals were not achieved in real world practice. **METHODS:** A retrospective study was performed on 662 medical records of patients with T2DM, diagnosed 24 to 48 months prior to signing the informed consent. The study included thirty-one general practitioner/specialist sites across Mexico, Argentina and Brazil. Inclusion criteria: age ≥21 years at diagnosis; complete record of pre-diagnosis medication and pre-existing CV risk factors and 2 years follow-up records. Exclusion criteria: type 1 diabetes; pregnancy; receiving antihyperglycemic agents or statins prior to diagnosis; initially treated with insulin after T2DM diagnosis; or clinical trial participation during the study period. Descriptive statistics were used for demographic/clinical characteristics. Kaplan-Meier test was used to examine time to treatment and cumulative treatment probability and multivariate logistic regression examined factors associated with such treatment. **RESULTS:** At diagnosis, patients had a mean age of 53 years; 44% had hypertension, 42% were obese and 23% had hypercholesterolemia. During the 2-year follow-up period, 93% were treated with OAHAs but only 29% of those eligible for statin therapy received statins. Time elapsed before first prescription of OAHA was 59±141 (Mean±SD) and 1 (1, 31) (median [IQR]) days and 230±232 days and 132 (30, 406) days for statin. No variables were associated with OAHA initiation but family history of T2DM and hypercholesterolemia at diagnosis were associated with statin initiation. No antihyperglycemic treatment intensification was recorded in 51%/53% of patients with HbA1c/FPG values above treatment targets during the follow-up period. **CONCLUSIONS:** The delay in treatment of hypercholesterolemia and intensification of treatment for hyperglycemia in patients with T2DM not attaining treatment targets works against effective prevention of chronic complications.

CV4

ECONOMICS OF DIABETES MELLITUS: THEORY AND EVIDENCE FOR BRAZILIAN DATA IN 2008

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INTRODUCTION: Diabetes Mellitus (DM) is characterized by the high level of blood glucose. Ministry of Health data estimated that Brazil had about 10 million DM cases

in 2010, being the fourth main cause of death. WHO estimated the prevalence of DM in Brazil is 10.2%, about 20 million people. **OBJECTIVES:** To measure the DM social cost based in earnings losses of Brazilian workers due to disease in 2008 using data from National Survey of Households (PNAD/IBGE). **METHODS:** A Binary Probit model to measure the participation in work force and a two-stage Heckman model to measure worked hours and productivity. Each model is estimated separately for both gender individuals, with and without disease, according three distinct definitions for DM: Restrict, Broad and Comorbidities. To capture the counterfactual effect, the model was calculated for ill and healthy individuals. The difference of both values exhibited the losses, which were aggregate to the whole population and the total cost was estimated. **RESULTS:** According each criterion, respectively, DM reduced the participation in the labor market in 0,97%; 4,60% and 7,06% for men and 0,14%; 4,79% and 6,44% for women, while reduced, respectively 1,51%; 6,40% and 9,15% in productivity and 6,44%; 15,23% and 17,58% in worked hours just for women. There was no impact of DM on productivity and in worked hours for men. The DM total cost was R$ 8,064 billion, or US$ 3,451 billion converted by current exchange rate. The losses reached 0,73% of total earnings and 0,27% of Brazilian GDP in 2008. **CONCLUSIONS:** DM generates significant losses in income of Brazilian workers, especially in relation to their participation in the labor market, since affects both of gender. The results indicate that public policies should be directed to disease diagnosis and prevention, since the development of comorbidities amplifies the effect of losses.

HEALTH TECHNOLOGY ASSESSMENT STUDIES

HT1

RAPID INCREASE OF HEALTH LITIGATION AS A MEANS OF MARKET ACCESS FOR INNOVATIVE MEDICINES IN COLOMBIA AND THE POTENTIAL ROLE OF HEALTH TECHNOLOGY ASSESSMENT

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OBJECTIVES: Reimbursement of high-cost medicines excluded from the Colombian mandatory healthcare plan (POS) through legal mechanisms known as 'tutela' and the Scientific Technical Committees (CTC) have significantly increased in the last four years. As the new healthcare statutory law (1751-2015) puts pressure on the healthcare budget, it is likely that these will increase further. This research analyses the "judicialisation" of the right to health in Colombia and the feasibility of a mandatory health technology assessment (HTA) evaluation as a policy to reduce reimbursement of non-POS medicines by litigation. **METHODS:** Secondary research of the main tutela decisions of the Colombian courts and CTC decisions related to non-POS medicines between 2011 and 2014 were conducted. A 2014 Ombudsman's Office report of detailed medicine-tutelas was also analysed, and cross-referenced with statistics from the Colombian Ministry of Health and the General Prosecutor. A lack of official data for 2014 is addressed using case-by-case tutelas, literature review and stakeholder interviews. **RESULTS:** Tutela and CTC decisions are predominantly in favour of protecting the fundamental right to health (80% of all decisions between 2011 and 2014), giving access to non-POS medicines irrespective of cost-effectiveness. According to the Ombudsman's Office, of the 115,147 tutelas presented in 2013, 34,099 (18.8%) were requests for medicines of which over half (22,685) were for access to non-POS medicine. The Colombian Fund of Solidarity and Guarantees paid health-promoting entities (EPS) over COP2 billion in 2012 and over 2.5billion in 2013 for the reimbursement of non-POS medicines following tutela and CTC decisions. **CONCLUSIONS:** Decisions over access to many high-cost medicines in Colombia are taken in courts based on infringement of fundamental rights rather than on cost and clinical-effectiveness assessments. This provides an important avenue to access new medicines, but also side-steps the formal reimbursement process. A more systematic, binding HTA system would likely reduce health litigation.

HT2

FROM LAW TO REALITY: MEASURING TIME-TO-ACCESS OF CONITEC APPROVED DRUGS IN BRAZILIAN PUBLIC HEALTH CARE SYSTEM (SUS) IN THE STATE OF PARANÁ

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OBJECTIVES: Brazilian Federal Law 12.401/2011 created the National Committee for Health Technology Incorporation (CONITEC) and defined criteria and deadlines for health technology (HT) incorporation in public health system (SUS). CONITEC advises the Brazilian Ministry of Health about HT incorporation or disinvestment in SUS and clinical guidelines development. After CONITEC appraises and recommends a technology, it should be available for the population in 180 days. The objective of this analysis was to evaluate the time between a technology was recommended by CONITEC and actually became available. **METHODS:** We reviewed all CONITEC's reports since 2012, and selected those regarding drugs. Reports were classified in not recommended and recommended, and publication date was retrieved for those recommended. Simultaneously, we evaluated the date a drug recommended by CONITEC was received by the Centro de Medicamentos Básicos do Paraná (CEMEPAR), which is responsible for buying and distributing medications in Paraná. The time between report publication and drug availability was then assessed. **RESULTS:** CONITEC published 125 reports since 2012, 93 on drugs and 42 classified as recommended. These 42 represented 62 drugs with different pharmacologic concentrations. From these, it was the Paraná state's liability to distribute 45, which were then selected for the analysis. The majority of cases (64.4%) were in non-conformity with established deadlines: 55.5% were unavailable at CEMEPAR before 180 days, and 8.9% were never bought until the day of this analysis (February 06th, 2015). The longest time between drug recommendation and its availability at CEMEPAR was 2 years and 73 days (salmeterol 50mcg) and the minimum was 13 days (adalimumab 40mg). Average time for a drug to be available for distribution was 315.3 days (135.3 days beyond the established deadline). **CONCLUSIONS:** This study shows that mere recommendation by CONITEC doesn't guarantee access for the population in the timeframe established. Reasons should be investigated.

HT4

PROCESO DE INCORPORACIÓN DE FÁRMACOS A LA LISTA POSITIVA DE MEDICAMENTOS (LPM) PARA LOS PRESTADORES INTEGRALES DE SALUD: EXPERIENCIA EN EL MINISTERIO DE SALUD PÚBLICA (MSP) DE URUGUAY

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OBJECTIVES: Describir el proceso para la de incorporación de fármacos al LPM en el marco del Sistema Nacional Integrado de Salud Uruguayo **METHODS:** El proceso comienza con la presentación de un formulario de solicitud al MSP al que se adjunta evidencia de alta calidad de su eficacia y seguridad comparado con las alternativas terapéuticas. Esta evidencia es analizada y complementada con una nueva búsqueda bibliográfica sistemática realizada por el evaluador. Se resumen los resultados de eficacia y seguridad obtenidos de estudios aleatorizados presentados y cuando hay más de uno y es metodológicamente adecuado se realizan meta análisis. Si no hay estudios de comparación cabeza a cabeza se realizan en ocasiones comparaciones indirectas. Los informes de eficacia y seguridad son posteriormente evaluados por un experto clínico quienes aportan su punto de vista en cuanto a la pertinencia de la inclusión. Finalmente en los casos candidatos a ingresar se realiza un análisis económico (impacto presupuestal o estudios de costo utilidad según el precio del tratamiento anual sea menor o supere un PBI per cápita). **RESULTS:** En 2011 solicitaron ingreso al FTM 123 fármacos, en 2012 fueron 37 fármacos, en 2013 fueron 30 fármacos y en 2014 fueron 51 lo que totaliza 241 solicitudes. De estas, todos fueron completamente revisados, 54 fueron rechazados por insuficiente evidencia presentada, 163 tienen informes de eficacia y seguridad completos y 24 están siendo evaluados en este sentido. De los 163 evaluados, 61 tienen pendientes evaluaciones clínica o económicas. **CONCLUSIONS:** El desarrollo de un sistema de evaluación de tecnologías para informar a los decisores sobre la incorporación de nuevos fármacos a las listas positivas de medicamentos de los sistemas únicos de salud, requiere de tiempo y pericia técnica, pero es posible en entornos de recursos limitados y representa un avance con respecto a modalidades anteriores.

PATIENT AND CLINICIAN PREFERENCES & QALY STUDIES

PP1

BARRIERS TO PARTICIPATION IN TRIALS OF CANCER: A SURVEY ON CLINICAL RESEARCH PERCEPTION

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OBJECTIVES: Clinical trials (CT) represent an important alternative treatment for oncologic patients. Also, CTs represent an important step to development of improved therapeutic strategies. On the other hand, little is known on Brazilian patient's perception regarding CT. Therefore, the aim of this survey was to describe the overall perception of clinical research in Brazil. **METHODS:** From April 2012 until October 2014, 254 respondents answered an internet-based survey related to knowledge related clinical research from Oncoguia Institute, an independent nonprofit cancer advocacy institution. **RESULTS:** Overall, about 85% of respondents would participate on oncology trial. Of all respondents, 99.9% believe that clinical research can contribute positively to advance of cancer treatment by increasing the scientific knowledge, improvement of treatment, finding a cure, to have a new treatment option, or improved quality of life. Among the respondents, 96% affirmed that have already had some information on clinical research, being internet the most used form of communication (69%), followed by physicians´ orientation (8%), magazines and newspaper (8%) and hospital hand-out material (7%). In addition, only 18 respondents reported previously participation on CT (6.9%), and about 10% answered that have someone known that participated in a clinical trial (e.g. friend, family or other). **CONCLUSIONS:** This survey demonstrates that respondents associate clinical research as an option in cancer treatment. However, only a small number of respondents have participated previously of a CT, besides that, internet was the main tool to learn about CTs. The data indicate that lack of available information, including low participation of physician on instructing their patients, are the current major barriers on CT in Brazil. Improvement of physician and patient awareness are potential solutions. Thus, strategies are needed to improve communication between patient and physician.

PP2

AN EQ-5D-5L VALUE SET BASED ON URUGUAYAN POPULATION PREFERENCES: REPORT OF THE FIRST EXPERIENCE IN LATIN AMERICA

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OBJECTIVES: To derive a value set from Uruguayan general population using the new five level (5L) EQ-5D instrument and report population norms. **METHODS:** We randomly assigned general population individuals to value 10 health states using composite Time Trade Off and 7 pairs of health states through Discrete Choice Experiments. Additionally, respondent provided sociodemographic information and rated their current health state. The sample was stratified using with quotas by location, gender, age and socioeconomic status in order to represent the Uruguayan population structure. Trained interviewers conducted face to face interviews using EuroQol valuation technology (EQVT) to administer the protocol, as well as to collect and store the data. Primary analysis used OLS and maximum likelihood robust regression models with or without interactions **RESULTS:** We included 794 respondents between 20 and 83 years. Their characteristics were